

**REMARKS**

After entry of this amendment, claims 1-35 will be pending for the Examiner's review and consideration. The Applicant would first like to thank the Examiner for allowance of claims 23-25 and the allowance of the subject matter disclosed within claims 8, 26, 28 and 30-32. The Office Action dated December 16, 2003 has been carefully considered. Claims 1 and 26 have been amended without prejudice. Claims 33-35 have been added. No new matter has been added. Reconsideration and allowance of the present application in view of the above amendments and the following remarks is respectfully requested.

In the Office Action dated December 16, 2003, the Examiner:

- objected to the amendment dated September 29, 2003 under 35 U.S.C. § 132 because it introduces new matter into the disclosure. Specifically, the Examiner objected to the inclusion of Figure 8a and all the amendments to the specification to support new Figure 8a;
- rejected claims 5, 7, 9-16, 19, 27, and 29 under 35 U.S.C. § 112 as failing to comply with the enablement requirement;
- rejected claims 1-4, 6, 17, 18 and 20-22 under 35 U.S.C. § 102(a) as being anticipated by WO 98/34552 to Ray ("Ray");
- allowed claims 23-25;
- objected to claim 8 as being dependent upon a rejected base claim, but otherwise allowable if rewritten in independent form; and
- objected to claims 26, 28, and 30-32 based upon a minor informality in claim 26 but otherwise allowable once corrected.

**35 U.S.C. § 132 Rejection**

The Examiner has objected to the amendment dated September 29, 2003 under 35 U.S.C. § 132 because it introduces new matter into the disclosure. Specifically, the Examiner objected to the inclusion of Figure 8a and all the amendments to the specification which accompanied the inclusion of Figure 8a.

It is respectfully requested that the amendment dated September 29, 2003 did not enclose any new matter. Specifically, Figure 8a and the accompanying amendments to the specification were added in response to the Examiner's objection that the drawings must show every feature of the invention specified in the claims.

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Furthermore, it is respectfully submitted that the amendment simply made explicit what was already implicit in the application - that one of ordinary skill in the art would have recognized that the general concepts disclosed within the specification relating to, *inter alia*, removable blades, varying blade insertion lengths, and varying blade angles would be equally applicable to all embodiments. Specifically, one of ordinary skill in the art would recognize that these general concepts could just as readily apply to the single blade embodiment as to the dual blade embodiment.

Moreover, support for the amendment dated September 29, 2003 can be found throughout the specification, for example, in discussing Figures 14-16, the specification states that "blades 244 of distractor 200 preferably are fixedly secured to jaws 214, such as by formation of blades 244 and jaws 214 as a unitary piece." This explicitly implies that the blades 244 do not have to be fixedly secured to the jaws 214. Thus, as one of ordinary skill in the art would recognize, the blades 244 could be removeably associated with the jaws 214 as previously disclosed within the specification. Furthermore, the specification consistently emphasizes that concepts disclosed in regards to the single blade embodiments are equally applicable to the dual blade embodiment depicted in Figures 14-16. For example, the specification states that vertebral engagers, transverse engagement walls, and/or the distractor mechanism previously disclosed are equally applicable to the dual blade embodiment. In addition, the specification states that "the foregoing description and drawings represent the preferred embodiments of the present invention [and that] it will be understood that various additions and/or substitutions may be made therein without departing from the spirit and scope of the present invention ... One skilled in the art will appreciate that the invention may be used with many modifications of structure, forms, arrangement, ... and components ... without departing from the principles of the present invention. The presently disclosed embodiments are therefore to be considered in all respects as illustrative and not restrictive ..." It is respectfully submitted that one of ordinary skill in the art would appreciate/recognize that removable blades, varying blade insertion lengths, and varying blade angles as described within the specification would be equally applicable to all embodiments disclosed within the specification.

Therefore, it is respectfully requested that this rejection be withdrawn.

**Independent Claim 1**

Independent claim 1 was rejected under 35 U.S.C. § 102(a) as being anticipated by Ray. Independent claim 1 has been clarified to recite a distractor comprising first and second handles; first and second jaws respectively associated with said first and second handles; a first set of blades extending from said first jaw; said first set of blades comprising at least a first blade and a second blade, said first and second blades being separated by a dimension sufficient to permit insertion of an implant therebetween; a second set of blades extending from said second jaw; said second set of blades comprising at least a first blade and a second blade, said first and second blades being separated by a dimension sufficient to permit insertion of the implant therebetween; and a distractor mechanism coupled between said handles and said jaws such that movement of said handles actuates said distractor mechanism to move said jaws apart, wherein said first and second sets of blades contact anatomical elements to be distracted and permit insertion of the implant between said anatomical elements. There is no disclosure, teaching, or suggestion in Ray of a distractor mechanism comprising a first set of blades extending from said first jaw; said first set of blades comprising at least a first blade and a second blade, said first and second blades being separated by a dimension sufficient to permit insertion of an implant therebetween; a second set of blades extending from said second jaw; said second set of blades comprising at least a first blade and a second blade, said first and second blades being separated by a dimension sufficient to permit insertion of the implant therebetween.

Rather, Ray discloses an insertion-distractor mechanism having, *inter alia*, tool tips 24 which are insertable into a fusion device comprising halves 10 and a core 27. In operation, a hole is pre-drilled into adjacent vertebrae sized and configured to receive the halves 10. Thereafter, the tool tips 24 are inserted into the halves 10 until a limit stop 22 abuts against a proximal slotted rib 11 formed in the halves 10. Therein, the tool tips 24 are used to spread apart the halves 10 and thus the adjacent vertebra which are engaged thereto so that the porous core 27 can be inserted therebetween. More specifically, Ray discloses an insertion-distractor mechanism including tool tips 24 wherein the tool tips 24 include a set of paired tips 32 sized and configured to engage notches 15 formed on both sides of an implant so that the paired tips 32 can be inserted into the implant. Thereafter, the tool tips 24 along with the implant are inserted into a hole pre-drilled in adjacent vertebra. Actuation of the insertion-distractor mechanism spreads apart the paired tips 32, which spreads apart the

implant halves 10, which causes the adjacent vertebra to spread apart so that a porous core 27 can be inserted between the fusion halves 10.

Thus, Ray does not disclose, teach, or suggest a distractor mechanism comprising a first set of blades comprising at least a first blade and a second blade, said first and second blades being separated by a dimension sufficient to permit insertion of an implant therebetween; and a second set of blades comprising at least a first blade and a second blade, said first and second blades being separated by a dimension sufficient to permit insertion of the implant therebetween.

Therefore, it is respectfully submitted that Ray does not disclose, teach, or suggest all of the elements of independent claim 1. Thus, it is respectfully submitted that independent claim 1 is allowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 1 is respectfully requested.

Claims 2-21 all ultimately depend from independent claim 1, and thus, it is respectfully submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 2-21 is therefore respectfully requested.

Moreover, newly added claims 33-35 have been added to further clarify the invention of independent claim 1, and as such, claims 33-35 all depend from independent claim 1. Thus, it is respectfully submitted that these claims are equally allowable. Therefore, allowance of claims 33-35 is respectfully requested.

#### **Independent Claim 22**

Independent claim 22 was rejected under 35 U.S.C. § 102(a) as being anticipated by Ray. Independent claim 22 recites a method of distracting adjacent vertebrae comprising the steps of, *inter alia*, providing a distractor; positioning said first set of spaced apart blades against spaced apart ends of a first vertebral endplate; positioning said second set of spaced apart blades against spaced apart ends of a second vertebral endplate adjacent and facing said first vertebral endplate; actuating said distractor mechanism to distract said first and second vertebral endplates; and inserting an implant between said first and second sets of blades and said first and second vertebral endplates. There is no disclosure, suggestion, or teaching in Ray of positioning said first set of spaced apart blades against spaced apart ends of a first vertebral endplate; positioning said second set of spaced apart blades against spaced apart ends of a second vertebral endplate; and actuating said distractor mechanism to distract said first and second vertebral endplates.

Rather, Ray discloses an insertion-distractor mechanism having, *inter alia*, tool tips 24 which are insertable into a fusion device comprising halves 10 and a core 27. In operation, a hole is pre-drilled into adjacent vertebrae sized and configured to receive the halves 10. Thereafter, the tool tips 24 are inserted into the halves 10. Thus, the tool tips 24 are used to spread apart the halves 10 and therein the adjacent vertebra which are engaged thereto so that the porous core 27 can be inserted therebetween. More specifically, Ray discloses an insertion-distractor mechanism including tool tips 24 wherein the tool tips include a set of paired tips 32 sized and configured to engage notches 15 formed on both sides of an implant so that the paired tip 32 can be inserted into the implant. Thereafter, the tool tips 24 along with the implant are inserted into a hole pre-drilled in adjacent vertebra. Therein, actuation of the insertion-distractor mechanism spreads apart the paired tips 32, which spreads apart the implant halves 10, which causes the adjacent vertebra to spread apart so that a porous core 27 can be inserted between the fusion halves 10. Ray does not disclose, teach, or suggest positioning said first set of spaced apart blades against spaced apart ends of a first vertebral endplate and positioning said second set of spaced apart blades against spaced apart ends of a second vertebral endplate.

Therefore, it is respectfully submitted that Ray does not disclose, teach, or suggest all of the elements of independent claim 22. Thus, it is respectfully submitted that independent claim 22 is allowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 22 is respectfully requested.

#### **Independent Claim 26**

Independent claim 26 was objected to because of a minor informality in language. Independent claim 26 has been amended to recite, *inter alia*, a distractor comprising a proximal end having first and second handles located in a first plane; a distal end having first and second jaws respectively associated with said first and second handles, said first and second jaws located in a second plane different from the first; wherein the first plane is angled with respect to the second plane so as to permit visualization of the blades from the proximal end.

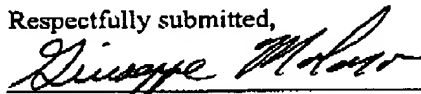
As independent claim 26 has been amended in accordance with the Examiner's instructions withdrawal of this rejection is respectfully requested. Thus, it is respectfully submitted that independent claim 26 is allowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 26 is respectfully requested.

Claims 27-32 all ultimately depend from independent claim 26, and thus, it is respectfully submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 27-32 is therefore respectfully requested.

In light of the above amendments and remarks, it is respectfully submitted that claims 1-35 are now in condition for allowance, and the Examiner is respectfully requested to reconsider this application with a view towards allowance. The Examiner is invited to call the undersigned attorney at 212-790-6348, if a telephone call could help resolve any remaining issues.

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